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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,968	12/21/2004	Guenter Frey	WP 21303 US	3000

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INDIANAPOLIS, IN 46204-5137

EXAMINER	
WALLENHORST, MAUREEN	

ART UNIT	PAPER NUMBER
1797	

NOTIFICATION DATE	DELIVERY MODE
12/17/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@uspatent.com
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Office Action Summary	Application No.	Applicant(s)	
	10/518,968	FREY ET AL.	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-39* is/are pending in the application.

4a) Of the above claim(s) *28-31 and 34-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-27,32 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/21/04, 3/21/05, 11/14/05, 2/9/07, 9/15/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Applicant's election without traverse of Group I, species A, claims 19-27 and 32-33, in the reply filed on November 26, 2008 is acknowledged.

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

3. Claims 23-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 23, the phrase "said special optical property" lacks antecedent basis since claim 23 depends from claim 19, and claim 19 only positively recites "a special property".

On line 2 of claim 24, the phrases "the wavelength range" and "the measurement signal" lack antecedent basis.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

> international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 19-25 and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Teodorcyzk et al (US 2003/0036202).

Teodorcyzk et al teach of a method for determining the concentration of an analyte in a sample, in particular for determining blood analytes such as glucose. In the method, a sample or a control fluid is introduced to a reagent test strip. The concentration of the analyte in the sample is determined, and the sample is identified as a control fluid or a test fluid. The control fluid comprises an aqueous solution having a predetermined amount of the analyte of interest, and in one embodiment, also includes a reflectance component that is capable of generating a reflectance profile different from the one generated by sample blood. The reflectance component is a suitable dye that is a modifier of reflectance and absorbance, wherein the dye has a maximum absorbance of light outside that of hemoglobin, particularly when the control fluid is one which is prepared to be suitable for use with colorimetric assays. Representative dyes include IR dyes such as copper phthalocyanine-3,4',4",4"'-tetrasulfonic acid and copper(II) phthalocyanine. After a sample fluid is introduced to the test strip, reagents on the test strip react with the analyte in either the sample or control fluid to produce a detectable product that is analyzed photometrically. The sample fluid is flagged to be either a control fluid or a test fluid by comparing reflectance values obtained to a reference value in order to derive the identity of the fluid. The reference value is a predetermined or standard signal which is known to a user and programmed in the meter, and to which the signal associated with the sample is compared. The reference value may be a reflectance value, and since the control fluid contains an IR dye that makes the reflectance profile of the control fluid different than the reflectance profile of the test

fluid, a comparison of the reflectance profile of the control fluid to the reference reflectance value will give a different result than the comparison of the reflectance profile of the sample fluid to the reference reflectance value. Once the signal or measurement has been obtained from the sample, the identity of the sample is determined based upon the obtained signal's relation to the reference reflectance value. A sample is identified as a control fluid if it is below a reference reflectance value and produces a reflectance profile representative of the IR dye present in the control fluid. A sample is identified as a test fluid if it is equal to or significantly higher than the reflectance reference value. See the abstract and paragraphs 0013, 0025-0026, 0041-0043, 0045, 0053 and 0055-0060 in Teodorcyzk et al.

7. Claims 19-21, 23, 27 and 32-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Modzelewski et al (US 2002/0160517, submitted in the IDS filed on December 21, 2004).

Modzelewski et al teach of a method for distinguishing between test types through spectral analysis. The method distinguishes between different types of test elements including analytical test strips having test fluids applied thereto and test strips having control fluids applied thereto, as measured by a reflectance-type testing device. The method utilizes a diagnostic test strip containing analytical chemistry upon which a fluid sample is placed. A chemical reaction occurs in the presence of a target analyte such as glucose to cause a change in the optical properties of the test strip. An optical photometric device then determines the analyte level of the sample by measuring an optical property, such as the intensity of reflected light at a certain wavelength from the test strip. The fluid sample is usually a fresh whole blood test sample or a control solution containing a known analyte concentration. The control solution is used to verify that the meter into which the test strip is inserted is performing within operational limits. The

method taught by Modzelewski et al serves to distinguish whether the control solution or the test sample solution has been applied to the test strip by inserting the test strip into an analytical meter system, measuring a first optical property of the test element, measuring a second optical property of the test element, and distinguishing either the control solution or the test solution on the test strip by identifying a predetermined relationship between the first and second optical properties. The first and second optical properties comprise the reflectance measurements of the sample fluid at both 610 nm and 660 nm. The sample solution is differentiated as a control solution or a test solution by analyzing aspects of the spectral curve derived from reflectance measurements taken from the test strip inserted into a meter system. Aspects of the spectral curve associated with an inserted test strip are ascertained by analyzing the reflectance measured over certain predetermined wavelengths or a wavelength range such as in the range of between 500 nm and 900 nm. Modzelewski et al teach that distinguishing between a control solution and a test solution is facilitated by incorporating a dye into a glucose control solution that serves to alter or distort the spectral curve of the control solution. The dye preferably has a narrow spectral absorbance so that it does not significantly impact the glucose evaluation of the sample. The distortion of the spectral curve of the control solution due to the dye provides a substantially different reflectance percentage value measured at 610 nm relative to that at 660 nm. Modzelewski et al teach that in normal blood samples, the percentage reflectance values measured at 610 nm and 660 nm are nearly the same, whereas in control solutions containing a dye, the percentage reflectance value at 610 nm is measurably different than the percentage reflectance value at 660 nm. The amount of difference between reflectance percentage values between the 610 nm channel and the 660 nm channel is dependent on the type and amount of dye

incorporated into the glucose control solution. The type and amount of dye used should be selected so that is does not exhibit significant absorbance at 660 nm. Figure 4 in Modzelewski et al depicts a graph of percentage reflectance vs. wavelength comparing the spectral curve of a blood test sample with a spectral curve of a glucose control solution having a dye therein. The samples illustrated have the same glucose concentration, as illustrated by the same measured percentage reflectance at 660 nm. The spectral curve for the blood test sample has approximately the same percentage reflectance values when measured using both 610 nm and 660 nm wavelengths. The spectral curve for the control solution with an added dye contains a deflection such that the reflectance percentage value at 610 nm is lower than the reflectance percentage value obtained at 660 nm. Based on this deflection of the spectral curve resulting from the dye, the meter system 10 is programmed to distinguish between a test sample and a control sample, and thus properly select the appropriate test, data processing protocol and related protocols. Any suitable dye can be used to modify the spectral curve of the glucose control solution, as long as it produces a detectable difference in measured results at two selected wavelengths in a reflectance spectral curve. See Figure 4 and paragraphs 0002, 0007-0008, 0012, 0021-0027, 0063-0067 and 0095-0102 in Modzelewski et al.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Teodorcyzk et al (US 2003/0036202). For a teaching of Teodorcyzk et al, see previous paragraphs in this Office action.

Teodorcyzk et al fail to teach that the IR dye in the control solution can be the specific one recited in instant claim 26. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to utilize any known IR dye as a reflectance component in the control solution taught by Teodorcyzk et al, including the known IR dye recited in instant claim 26, since Teodorcyzk et al teach that the IR dye utilized in the control solution is not limited so long it is capable of generating a reflectance profile different from the one generated by sample blood.

11. Claims 22 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Modzelewski et al in view of Teodorcyzk et al. For a teaching of Modzelewski et al in view of Teodorcyzk et al, see previous paragraphs in this Office action.

Modzelewski et al fail to teach that the dye included in the control solution can be an IR dye, such as one of the dyes recited in instant claims 22 and 24-26. However, based upon the combination of Modzelewski et al in view of Teodorcyzk et al, it would have been obvious to

one of ordinary skill in the art at the time of the instant invention to use one of the IR dyes recited in instant claims 22 and 24-26 as the dye in the control solution taught by Modzelewski et al since Modzelewski et al teach that any dye that serves to change the reflectance spectral curve of a control solution so as to differ from the reflectance spectral curve of a test solution can be used, and Teodorcyzk et al teach that IR dyes incorporated into a control solution serve to spectrally distinguish a control solution from a test solution by modifying the reflectance and absorbance values of the control solution to differ from that of a test solution.

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Rannikko et al who teach of a control solution for photometric analysis, Marfurt who teaches of a method for distinguishing a control solution from a sample solution, and Mast who teaches of a liquid control solution for glucose measurement that contains glucose and a dye. It is noted that the effective filing date of the instant application is before the publication date of Marfurt.

Applicants are informed that on the Information Disclosure Statement (IDS) filed on November 14, 2005, several references have been crossed out since these same references were already considered and made of record on the IDS filed either December 21, 2004 or March 21, 2005.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1797

mmw

December 11, 2008

/Maureen M. Wallenhorst/

Primary Examiner, Art Unit 1797